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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,513	08/06/2002	Peter Brossart	WWELL52.001APC	8680

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/019,513	BROSSART ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 7/20/05,2/22/06 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *September 22, 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *1 and 15*.
   Claim(s) withdrawn from consideration: *21,24,27,29 and 31*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Susan Ungar
Primary Examiner
Art Unit: 1642

Continuation of 5. Applicant's reply has overcome the following rejection(s): The reply has overcome the objections to the term adjuvans and galenicals on page 2, section 4 of the previous action..

Continuation of 11. does NOT place the application in condition for allowance because, (a) as drawn to the response filed July 20, 2005, Applicant argues that clinical results are submitted, Wierecky et al, Cancer Immunol., Immunother, 2005, using SEQ ID NOS 1 and 2 of the present application wherein the publication demonstrates that objective clinical responses can be achieved in late-stage patients (stage IV renal cell carcinom) and the evidence directly rebuts the Examiner's assertion that the claimed peptide would not be effective against a tumor in situ. The argument has been considered but has not been found persuasive. Although the paper has not been entered, a brief review reveals that the submitted evidence is not commencerate in scope with the claimed invention. The claimed invention is a nine amino acid polypeptide and that polypeptide in a pharmaceutical composition. The submitted evidence, on the other hand is drawn to a method of treating cancer with a therapeutic which comprises two novel 9-mer peptides which have been pulsed into dendritic cells (wherein it does not appear that any nexus is provided in the submitted evidence between SEQ ID NO:1 and either of the nin-mers disclosed) wherein administration of the combined dendritic cells resulted in a clinical effect. Nothing in the reference suggests that SEQ ID NO:1 alone would be effective in treating cancer, would be effective in raising an effective T-cell response and for the reasons of record, the claims are not enabled.
Applicant argues that Examiner appears to think that the present invention lacks enablement due to escape of the cells by deficient antigen presentation, that is that antigen presentation would be required. Applicant states that the expression of MUC1-protein at the cellular surface is irrelevant for the recognition of the tumor cells by either CD8+ or CD4+ T-cells which recognize peptides in conjunction with HLA class I or HLA class II molecules respectively. Applicant further states that it is crucial that short peptides of MUC1, such as the one that is claimed, are generated from intracellular cources of polypeptide proteins. The argument has been considered but has not been found persuasive, because neither the specification nor the art of record disclose that SEQ ID NO:1 is a short peptide that is generated from intracellular sources of polypeptide proteins presented in vivo in cancer cells. Further, Examiner never limited the discussion of antigen presentation to antigen alone on the cell surface. It is suggested that Applicant review the paragraph bridging pages 4 and 5 of the final office action, in particular the teachings of the abstracts of SEmino et al, Algarra et al and Bodney et al.
Applicant argues that the claimns are not drawn to providing a cure for cancer. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claims or issues discussed in the prior Office Action and for the reasons of record, the claims are not enabled.
Applicant states that the specification teaches that co-stimulators are required and that the co-stimulators are dendritic cells. Applicant argues that dendritic cells may be recruited to the site of injection of a pharmaceutical product containing peptides as the sole active ingrediant and that this approach is feasible. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claims as currently constituted.
Applicant argues that scientific results that show the suitability of HLA-A*02-restricted peptides as vaccines in cancer-immunotherapy are published. The argument has been considered but has not been found persuasive since none of the peptides discussed are SEQ ID NO:1 and for the reasons of record, the claims are not enabled.
Applicant argues that the person skilled in the art would be able to practice the claimed invention based upon the description in the specification. The argument has been considered but has not been found persuasive for the reasons set forth previously and above.
Applicant argues that the clinical evidence obtained using the peptide of the claimed invention directly rebuts the Eaminer's position that the claimed invention is not enabled for in vivo disease treatment. The argument has been considered but has not been found persuasive because the evidence submitted is not commensurate in scope with the claimed invention.

As drawn to the response and Declaration filed February 22, 2006

Applicant argues and the Declaration states that in view of the submitted evidence, that claims 21, 24, 27, 29, 31 should be rejoined and allowed. Dr. Brossart submits Broussart et al, Cancer Research, 2001 and argues that in vitro induced MUC1 specific T cells, induced in vitro with SEQ ID NO:1 and 2 peptide pulsed dendritic cells were tested against primary cancer cells and in vitro lysed the cancer cells, therefore, suggesting that the claimed invention is enbled for a pharmaceutical composition and methods for treating cancer. The argument has been considered but is not found persuasive because the evidence presented is not commensuate in scope with the claimed invention. Nothing in the reference suggests that SEQ ID NO:1 alone would be effective in treating cancer, would be effective in raising an effective T-cell response and for the reasons of record, the claims are not enabled. .